

REMARKS

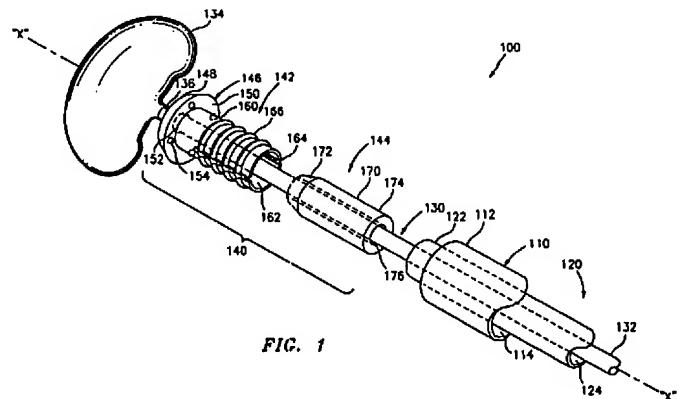
The present application has been reviewed in light of the Office Action dated March 29, 2010. Claims 1-8 and 10-27 are currently pending, of which claims 1, 17 and 22 have been amended herein. Claim 9 has been cancelled herein. In view of the amendments above and the remarks to follow, Applicant respectfully requests reconsideration and allowance of this application.

Claims 22-27 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,428,550 to Vargas et al. (hereinafter “Vargas”). Applicant respectfully submits that independent claim 22, as amended herein, is allowable over Vargas because Vargas fails to disclose each and every feature of independent claim 22. Accordingly, the rejection of independent claim 22, under 35 U.S.C. § 102(b), should be withdrawn.

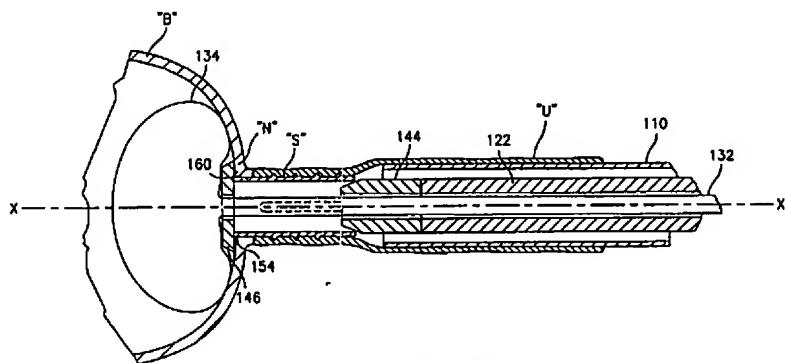
Pursuant to 35 U.S.C. § 102, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP § 2131. Applicant respectfully submits that Vargas fails to disclose each and every element recited by independent claim 22 as required by 35 U.S.C. § 102.

Independent claim 22 recites an anchoring assembly for use in a surgical anastomosis procedure including, *inter alia*, “a flange member having a head portion . . . protruding laterally from [an] expandable annular body and defining proximal and distal end surfaces, the proximal end surface including a plurality of protuberances formed thereon and extending proximally therefrom.” The embodiment of apparatus 100 depicted in FIG. 1 reproduced below includes a flange member 142 having a head portion 146 protruding laterally from an expandable annular body 160. The head

portion 146 defines a distal end 148 and a proximal surface 150, which includes a plurality of protuberances 154 formed thereon and extending proximally therefrom.



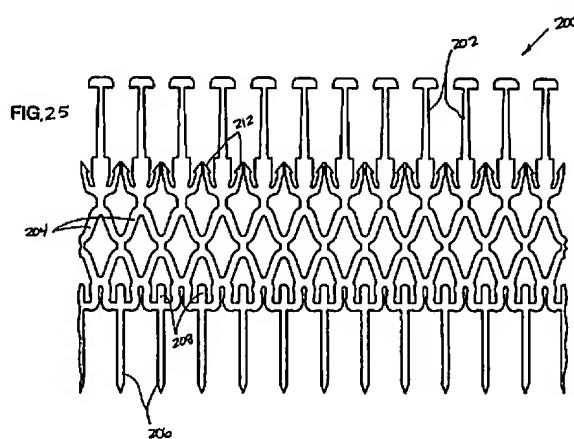
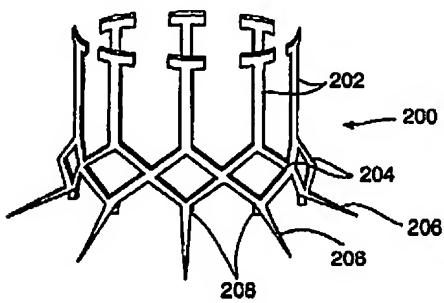
Since the protuberances 154 extend proximally from the proximal surface 150, the head portion 146 may engage a bladder neck "N" in the manner depicted in FIG. 3B reproduced below. The proximal surface 150 engages the inner surface of the bladder neck "N" while the protuberances 154 grip and dig into the bladder neck "N" as described in paragraph [0044] of Applicant's specification.



In contrast to independent claim 22, Vargas discloses the anastomosis device 200 depicted in FIG 24 reproduced below, and the modified anastomosis device 200 depicted in FIG. 25. The device

200 of FIG. 24 is depicted in a deployed configuration wherein distal needles 206 are bent outward, and proximal pull tabs 202 are arranged vertically in a cylindrical configuration. The pull tabs 202 may be folded downward and radially outward (see col. 10, lines 19-23) to a second deployed configuration where the pull tabs trap the wall of a target vessel between the needles 206 and the pull tabs 202.

FIG. 24

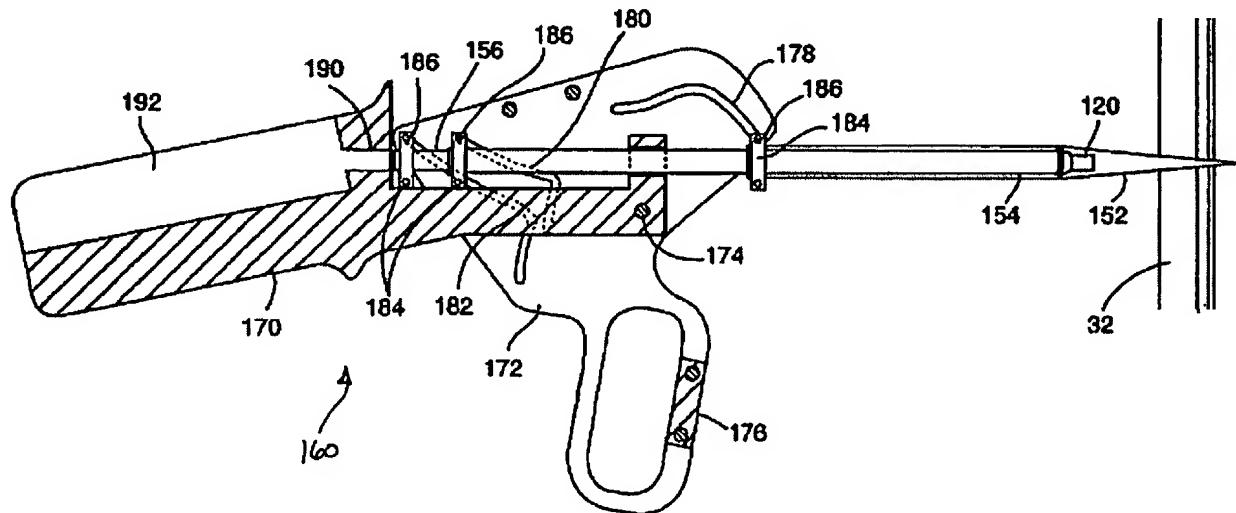


According to the Examiner, the device 200 depicted in FIG. 25 includes protuberances or horns 212 on a head portion (see page 8 of the Office Action). Applicant respectfully submits, however, that the horns 212 of Vargas do not satisfy the limitations of the “protuberances” recited in independent claim 22. Firstly, the horns 212 of Vargas are not disposed on a “head portion protruding laterally” from an annular body when the device 200 is in the deployed configuration of FIG. 24, i.e., when the pull tabs 202 are disposed vertically in a cylindrical configuration. Rather, the pull tabs 202 and the horns 212 are laterally aligned with an annular diamond linkage 204. Furthermore, Applicant respectfully submits that when the device 200 is moved to the second deployed configuration, i.e., when the pull tabs 202 are folded downward, the horns 212 are not

“extending proximally” from a “proximal end surface” of a head portion. Rather, the horns 212 would, at best, extend radially outward along with the pull tabs 202.

In addition, the expander 210 and expander tube 156 disclosed by Vargas are attached to the handle of the device and do not remain in the body. FIG. 19 of Vargas, reproduced below, shows expander tube 156 extending into the handle of the device.

FIG. 19



By contrast, claim 22 requires that the locking member is secured within the annular body. Vargas discloses that expander 210 is used to bend the needles 206: “it should be understood that an outer diameter of the expander 210 according to this embodiment can be equal to or smaller than an inner diameter of the device 200 and can bend the needles 206 outward without radially expanding the device.” Col 10, lines 15 through 19. The expansion of the device is unimportant because the needles, rather than the radial expansion of the device, are depended upon to secure the device within

the blood vessel. Applicants submit that Vargas does not disclose a locking member secured within the passage of the annular body.

In view of the foregoing, Applicant respectfully submits that each and every feature of independent claim 22 is not taught or disclosed by Vargas in that Vargas fails to teach or disclose a “plurality of protuberances . . . extending proximally” from a “proximal end surface” of a “head portion protruding laterally from the expandable annular body.” Accordingly, Applicant respectfully submits that independent claim 22 is patentably distinguishable over Vargas, and therefore allowable over Vargas under 35 U.S.C. § 102(b).

As claims 23-27 depend, directly or indirectly, from claim 22 and contain all of the features of independent claim 22, Applicant respectfully submits that claims 23-27 are also allowable over Vargas under 35 U.S.C. § 102(b).

Claims 1, 3-8, 10-11 and 13-15 stand rejected under 35 U.S.C. § 103(a) over Vargas in view of U.S. Patent No. 6,695,867 to Ginn et al. (hereinafter “Ginn”). Applicant respectfully submits that independent claim 1 is allowable under 35 U.S.C. § 103(a) over Vargas in view of Ginn.

Independent claim 1 recites an apparatus for performing a surgical anastomosis including, *inter alia*, “a flange member having an expandable annular body and a head portion . . . protruding laterally therefrom, . . . the head portion defining proximal and distal end surfaces, the proximal end surface including a plurality of protuberances formed thereon and extending proximally therefrom.” As discussed above with reference to claim 22, Vargas fails to disclose a “plurality of protuberances .

.. extending proximally" from a "proximal end surface" of a "head portion protruding laterally from the expandable annular body."

The Examiner relies on Ginn for the disclosure of "an expansion assembly having a tubular body and an expandable tip." The Examiner relates an obturator 218 (see FIG. 10 reproduced below) of Ginn with an "expandable tip" (see page 5 of the Office Action).

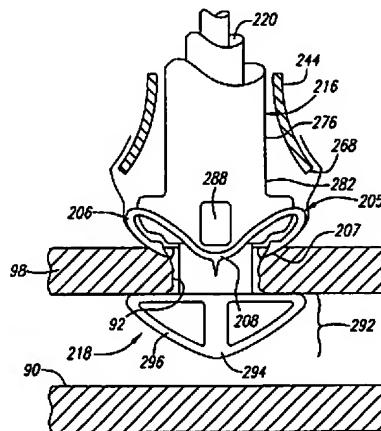


FIG. 10

Applicant respectfully submits that even if Ginn does disclose an expandable tip, Ginn fails to cure the deficiencies of Vargas in that Ginn does not disclose a plurality of protuberances . . . extending proximally" from a "proximal end surface" of a "head portion protruding laterally from the expandable annular body," as recited in claim 1.

Ginn discloses a ramped proximal surface 50a that deflects the tines 7 and/or the entire clip 5 radially outward. This directs the tines into the tissue. However, Ginn does not disclose that "the

locking member is maintained in the annular body to maintain the annular body in the expanded configuration,” as recited in the claims.

Accordingly, Applicant respectfully submits that independent claim 1 is patently distinguishable from Vargas in view of Ginn, and therefore allowable over Vargas in view of Ginn under 35 U.S.C. § 103(a). As claims 3-8, 10-11 and 13-15 depend, directly or indirectly, from independent claim 1 and contain all of the features of independent claim 1, Applicant respectfully submits that claims 3-8, 10-11 and 13-15 are also allowable over Vargas in view of Ginn under 35 U.S.C. § 103(a).

Claims 2 and 12 stand rejected under 35 U.S.C. § 103(a) over Vargas in view of Ginn and in further view of U.S. Patent No. 6,206,913 to Yencho et al. (hereinafter “Yencho”). Applicant respectfully submits that claims 2 and 12 are allowable under 35 U.S.C. § 103(a) over Vargas in view of Ginn and Yencho.

The Examiner relies on Yencho for the disclosure of a balloon as expandable tip (claim 2) and helical slot (claim 12) defined within the annular body (see page 7 of the Office Action). Applicant respectfully submits that even if Yencho does disclose a balloon expandable tip and a helical slot defined within an annular body, Yencho fails to cure the deficiencies of Vargas in view of Ginn in that Yencho does not disclose a plurality of protuberances . . . extending proximally” from a “proximal end surface” of a “head portion protruding laterally from the expandable annular body” as recited in independent claim 1, from which claims 2 and 12 depend. Accordingly, Applicant respectfully submits that the subject matter of claims 2 and 12, as a whole, is patently distinguishable

from Vargas in view of Ginn and Yencho, and therefore claims 2 and 12 are allowable over Vargas in view of Ginn and Yencho under 35 U.S.C. § 103(a).

Claim 16 stands rejected under 35 U.S.C. § 103(a) over Vargas in view of Ginn and in further view of U.S. Patent No. 6,629,988 to Weadock (hereinafter “Weadock”). Applicant submits that claim 16 is allowable under 35 U.S.C. § 103(a) over Vargas in view of Ginn and Weadock.

The Examiner relies on Weadock for the disclosure of an anchoring assembly made from a bio-absorbable material. Weadock relates generally to an anastomosis type staple. Applicant submits that even if Weadock does disclose an anastomosis type staple (e.g., anchoring assembly) made from bio-absorbable materials, Weadock fails to cure the deficiencies of Vargas in view of Ginn in that Weadock does not disclose a plurality of protuberances . . . extending proximally” from a “proximal end surface” of a “head portion protruding laterally from the expandable annular body” as recited in independent claim 1, from which claim 16 depends.

Accordingly, in view of the foregoing, since Weadock fails to cure the deficiencies of Vargas in view of Ginn, Applicant submits that the subject matter of claim 16, as a whole, is allowable under 35 U.S.C. § 103(a) over Vargas in view of Ginn and Weadock.

Claims 17-21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Vargas in view of Ginn and in further view of U.S. Patent No. 5,591,179 to Edelstein (hereinafter “Edelstein”). Applicant respectfully submits that independent claim 17 is allowable under 35 U.S.C. § 103(a) over Vargas in view of Ginn and Edelstein.

Independent claim 17 recites a method for performing a surgical anastomosis including, *inter alia*, the step of providing an apparatus having “a flange member having an expandable annular body and a head portion . . . protruding laterally therefrom, . . . the head portion defining proximal and distal end surfaces, the proximal end surface including a plurality of protuberances formed thereon and extending proximally therefrom.” As discussed above with reference to claim 1, Vargas in view of Ginn fails to disclose a “plurality of protuberances . . . extending proximally” from a “proximal end surface” of a “head portion protruding laterally from the expandable annular body.”

The Examiner relies on Edelstein for the disclosure of “passing an anastomosis device through a body lumen” (page 11 of the Office Action). Edelstein relates to a device for deploying a needle and suture to suture the urethral stump and bladder to one another. Applicant submits, however, that even if Edelstein does disclose “passing an anastomosis device through a body lumen,” Edelstein fails to cure the deficiencies of Vargas in view of Ginn in that Edelstein fails to disclose providing an apparatus having “a flange member having an expandable annular body and a head portion . . . protruding laterally therefrom, . . . the head portion defining proximal and distal end surfaces, the proximal end surface including a plurality of protuberances formed thereon and extending proximally therefrom.”

Accordingly, Applicant respectfully submits that independent claim 17 is patentably distinguishable over Vargas in view of Ginn and Edelstein, and therefore allowable over Vargas in view of Ginn and Edelstein under 35 U.S.C. § 103(a). As claims 18-21 depend, directly or indirectly, from claim 17 and contain all of the features of independent claim 17, Applicant

respectfully submits that the subject matter of claims 18-21, as a whole, is also allowable over Vargas in view of Ginn and Edelstein under 35 U.S.C. § 103(a).

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims pending in this application, namely Claims 1-8 and 10-27, are in condition for allowance. Accordingly, early and favorable reconsideration of this application is respectfully requested. Should the Examiner feel that a telephone or personal interview may facilitate resolution of any remaining matters, he or she is respectfully requested to contact Applicant's attorney at the number indicated below.

Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 21-0550 therefor.

Application No. 10/516,437
Amendment dated May 25, 2010
Reply to Final Office Action of March 29, 2010

An early and favorable response on the merits is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Francesco Sardone".

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